Ten-Year Follow-up of Laser In Situ Keratomileusis for Myopia of up to −10 Diopters

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• PURPOSE: To evaluate the long-term outcomes of laser in situ keratomileusis (LASIK) for myopia of up to −10 diopters (D).

• DESIGN: A long-term (10-year) follow-up retrospective, interventional case series.

• METHODS: The study included 97 eyes of 70 patients with a preoperative spherical equivalent (SE) of up to −10 D treated with myopic LASIK at the Instituto Oftalmológico de Alicante, Alicante, Spain, using the VISX 20/20 excimer laser (Santa Clara, California, USA) and the Automated Corneal Shaper microkeratome (Chiron Vision, Irvine, California, USA). All patients were evaluated three months, one year, two years, five years, and 10 years after surgery. The main outcome measures were refractive predictability and stability, mean corneal keratometry, topographical cylinder, safety, efficacy, stability of visual acuity, and postoperative complications.

• RESULTS: At 10 years, 71 (73%) of 97 eyes were within ± 1.00 D and 89 (92%) were within ± 2.00 D. Twenty eyes (20.8%) underwent retreatments because of overcorrection, undercorrection, regression, or both. The mean SE slightly decreased (myopic regression) over 10 years, with a mean myopic regression of −0.12 ± 0.16 D per year. Fifty-four (54.6%) of 97 eyes demonstrated an increase in best spectacle-corrected visual acuity (BSCVA) after 10 years. No eye developed corneal ectasia in the long-term, and only three eyes lost more than two lines of BSCVA because of complications that were not attributable to the LASIK procedure.

• CONCLUSIONS: LASIK for myopia of up to −10 D is a safe and effective procedure with slight myopic regression that slows down with time and a high rate of BSCVA increase in the long-term. (Am J Ophthalmol 2008;145:46–54. © 2008 by Elsevier Inc. All rights reserved.)

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EXCIMER LASER PHOTOREFRACTIVE KERATECTOMY (PRK) began to gain popularity in the early 1990s to correct low to moderate myopia. Laser in situ keratomileusis (LASIK) was introduced with claimed advantages over PRK such as quick visual rehabilitation, minimal postoperative discomfort, and the ability to correct high degrees of myopia with little postoperative corneal haze.[1–4] Therefore, at that time, PRK was performed mostly by us for low to moderate myopic corrections, whereas LASIK, based on the principle of keratomileusis, was preferred over PRK for high myopic corrections. Since the early 1990s, approximately 18 million LASIK procedures have been performed worldwide, with eight million in the United States alone.[5]

Although the risks associated with LASIK are considered to be low, postoperative flap-related complications can be sight threatening.[2–4] Also, it is suggested that excessive photoablation may result in iatrogenic keratectasia with a progressive increase in myopia.[4,6,7] Despite millions of procedures performed, to the best of our knowledge, few studies with five- to six-year follow-up have documented reasonably good results with LASIK for moderate myopia.[8–10] Further, to the best of our knowledge, the long-term outcomes (refractive stability, efficacy, and safety) of LASIK are not known.

The aim of this study was to evaluate the long-term (10-year) predictability, stability, safety, and efficacy of LASIK for myopia of up to −10 diopters (D), with special interest in the analysis of regression and the differences in evolution between eyes with and without retreatments.

METHODS

• PATIENT POPULATION: The global study included 294 eyes of 178 patients treated with myopic LASIK at the Instituto Oftalmológico de Alicante, Alicante, Spain, between April 1, 1992 and December 31, 1995. The patients returned for follow-up at three months, one year, two years, five years, and 10 years after the initial procedure, either spontaneously or after telephone calls (particularly at 10 years). Among this group, 97 eyes (47 right, 50 left) of 70 consecutive patients who had a myopic spherical equivalent (SE) up to −10 D with the information at each time gate or just at the 10-year visit (availability of preoperative and postoperative topography maps at the 10-year follow-up) were included in this work. No patients

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TABLE 1. Patient Demographics of the 97 Eyes before Laser In Situ Keratomileusis for Myopia of up to −10 Diopters

Characteristics	Data
Mean age ± standard deviation (range), yrs	33.2 ± 9.9 (17 to 57)
Gender	
Male	33
Female	36
Mean sphere ± standard deviation (range), D	−6.53 ± 1.82 (−1.00 to −9.50)
Mean cylinder ± standard deviation (range), D	−1.44 ± 1.07 (0 to −5.00)
Mean SE ± standard deviation (range), D	−7.27 ± 1.94 (−1.63 to −9.88)

D = diopters; SE = spherical equivalent; yrs = years.

were excluded other than those who did not comply with the inclusion criteria.

Patient demographics and refraction at the time of treatment are given in Table 1. Inclusion criteria for surgery were: no contact lens wear four weeks before the surgery and stable refractive error for at least six months before surgery, normal peripheral retina or treated with photocoagulation when necessary, no previous ocular surgery, no corneal diseases, no glaucoma, or history of ocular trauma. Informed consent was obtained from all patients after they received a detailed description of LASIK and a thorough review of its known risks. Exclusion criteria for surgery were: evidence of keratoconus or keratoconus suspect as evidenced by corneal topography, active ocular or systemic disease likely to affect corneal wound healing, calculated postoperative corneal residual stromal bed (RSB) thickness of less than 250 μm, pregnant, or nursing.

• **SURGICAL PROCEDURE:** The day before surgery, diclofenac sodium 0.1% drops (Voltaren; Novartis AG, Basel, Switzerland) and trimethoprim and polymyxin B eye drops (Oftalmotrim; Cusi, Barcelona, Spain) were instilled. The procedure was carried out using topical anesthesia of oxybuprocaine 0.4%.

All surgeries were performed by three surgeons (J.L.A., J.J.P.-S., A.A.) using the same technique and same protocol.[11] An 8.5- to 9.0-mm diameter superiorly hinged anterior corneal flap was created in thickness using the Automated Corneal Shaper (ACS; Chiron Vision, Irvine, California, USA) microkeratome, with either 130- or 160-μm head, in every patient.

A 193-nm VISX 20/20 excimer laser (VISX, Inc, Santa Clara, California, USA) with software version 3.2 was used. Calibration was carried out at the beginning of each surgical session. The eyelids were retracted with a speculum. During surgery, patients fixated on the laser's helium–neon fixation light. Ablation was achieved using a beam with fluence of 160 mJ/cm^2 at an ablation rate of 5 Hz. Astigmatism was corrected by sequential ablation with an area of 6.0 × 4.5 mm. The mean optical zone was 5.95 ± 0.18 mm (range, 5.0 to 6.00 mm), and the mean ablation depth was 91 ± 22 μm (range, 25 to 163 μm).

After surgery, tobramycin (Tobrex; Alcon Laboratories, Fort Worth, Texas, USA) and diclofenac 0.1% (Voltaren; Novartis AG) drops were used. Dexamethasone 0.1% was used four times daily during the first week. Subsequently, fluorometholone 0.25% was applied four times daily for a minimum of four weeks based on the refraction and intraocular pressure. The steroid dose was tapered gradually (thrice and twice daily for two weeks each).

• **RETREATMENTS:** The criteria for retreatment always included one of the following three parameters: 1) manifest SE of −1.00 D or more; 2) uncorrected visual acuity (UCVA) of 20/40 or less; and 3) patient dissatisfaction with the visual result. Undercorrection was defined as an SE of −1.00 D or more at the first postoperative visit (at three months). Regression was noted when a 0.50D or more myopic shift occurred between follow-up visits without retreatment.

LASIK retreatments were performed by lifting the flap and reablating the stromal bed. Before surgery, the edge of the flap was marked with gentian violet on the temporal side. A flat spatula was used to lift the corneal flap. The stromal bed then was ablated using one of the excimer laser system: VISX 20/20 excimer laser (eight retreatments), NIDEK EC-5000 (NIDEK Co, Gamagori, Japan; three retreatments), Technolas 217 (Bausch & Lomb, Rochester, New York, USA; eight retreatments), and Esiris Scwhind (SCHWIND Eye-Tech-Solutions, Kleinostham, Germany; two retreatments). After ablation, the flap was replaced in its original position, and the interface was irrigated copiously.

• **POSTOPERATIVE EVALUATION:** All patients were evaluated three months, one year, two years, five years, and 10 years after LASIK, which included measurement of manifest refraction, cycloplegic refraction, UCVA, best spectacle-corrected visual acuity (BSCVA), slit-lamp biomicroscopy, dilated funduscopy, applanation tonometry, and corneal thickness using DGH-500 pachymeter (DGH Technology, Inc, Exton, Pennsylvania, USA) or Alcon Ocuscan RxP Ophthalmic Ultrasound System (Alcon Laboratories, Inc). Visual acuity was measured using a standard Snellen acuity chart at 6 m. All patients underwent corneal topography evaluation using EyeSys topographer (EyeSys Corneal Analysis System, Houston, Texas, USA; before surgery to five years of follow-up), Orbscan I slit-scanner (Bausch & Lomb; only at five or 10 years of follow-up), and CSO corneal topography system (CSO, Firenze, Italy; only at 10 years of follow-up).

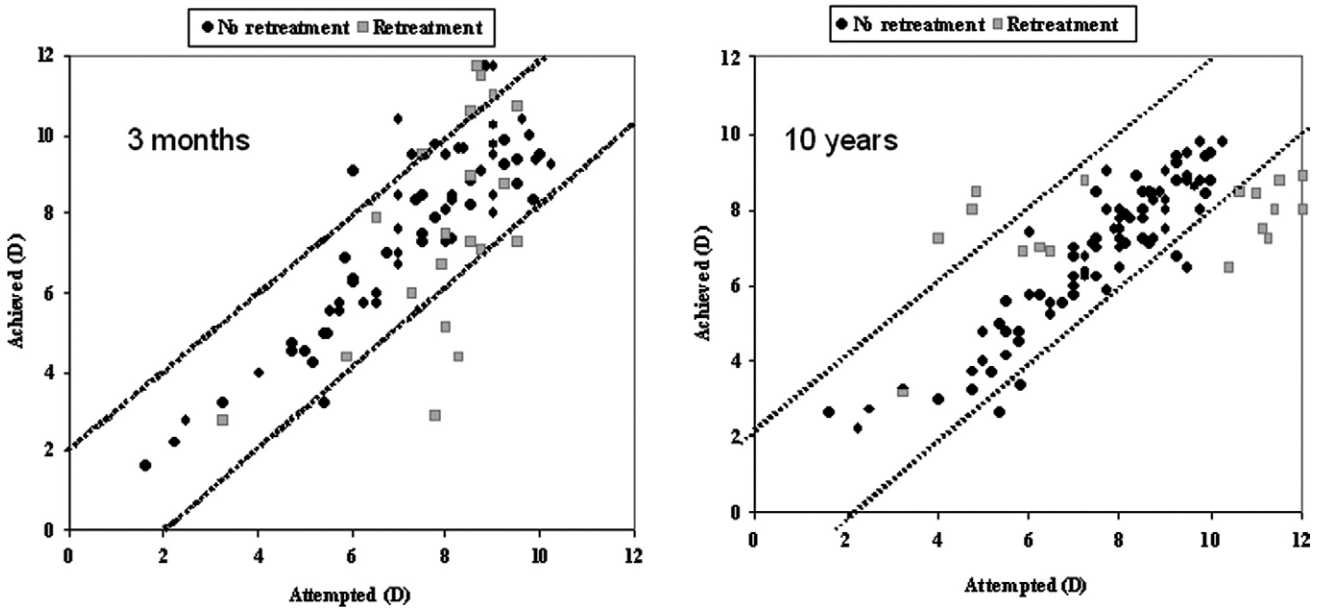

FIGURE 1. Scattergrams showing attempted vs achieved correction at (Left) three months and (Right) 10 years after laser in situ keratomileusis (LASIK) for the 97 myopic eyes in the study. Retreatments are represented separately. D = diopters.

Residual stromal bed thickness was estimated by two methods: 1) preoperative pachymetry minus predicted flap thickness (according to Pérez-Santonja and associates,[11] who found a mean flap thickness of 114 ± 17 μm for the 160-μm head and 88 ± 12 μm for the 130-μm head for the ACS microkeratome) minus calculated ablation depth and 2) postoperative pachymetry (using the latest available pachymetry) minus predicted flap thickness. If enhancement procedures were performed, the RSB was estimated using the sum of the calculated ablation depths for all procedures.

Corneal ectasia was defined as inferior topographic steepening of 5 D or more compared with the immediate postoperative appearance, loss of two or more Snellen lines of UCVA, and a change in manifest refraction of 2 D or more in either sphere or cylinder.[12]

Patients were examined and evaluated by independent examiners at each follow-up. Data were obtained at the end of 10 years and were evaluated retrospectively regarding the format for reporting refractive surgical data[13,14] and including the safety and efficacy indexes: Safety = ($BCVA_{postoperative}$/$BCVA_{preoperative}$); Efficacy = ($UCVA_{postoperative}$/$BCVA_{preoperative}$). Also, the results of eyes that underwent retreatment (retreatment group) and that did not undergo retreatment (no retreatment group) were compared.

• **STATISTICAL ANALYSIS:** Data analysis was performed using SPSS for Windows version 11.0 (SPSS, Inc, Chicago, Illinois, USA). Normality was checked by the Shapiro–Wilk test, Kolmogorov-Smirnov test, and normal probability plots. The Mann–Whitney *U* test was performed to compare no retreatment and retreatment groups. Correlations were tested using the Spearman correlation coefficient. Differences were considered to be statistically significant when the *P* value was $< .05$.

RESULTS

• **RETREATMENTS, REFRACTIVE STABILITY, AND PREDICTABILITY:** Scattergrams of attempted vs achieved correction at three months and 10 years after surgery are illustrated in Figure 1. Twenty (20.6%) of 97 eyes (16 of 70 patients) underwent retreatments. Eighteen eyes (90%) of 18 patients underwent only one retreatment, and two eyes (10%) of one patient underwent two retreatments. The indications for retreatment were undercorrection in eight eyes (40%) of eight patients, followed by regression in three eyes (17.5%) of three patients, both overcorrection and regression in three eyes (15%) of two patients, overcorrection in four eyes (22.2%) of four patients, and mixed astigmatism in two eyes (11.1%) of one patient. Eleven eyes of 11 patients underwent retreatment between three months and one-year follow-up, four eyes of four patients between one-year and two years follow-up, two eyes of two patients between two years and five years follow-up, and five eyes of three patients after five years follow-up. Regarding the predictability, the percentage of eyes within ± 0.50 D, ± 1.00 D, ± 2.00 D emmetropia after 10 years is demonstrated in Figure 2.

After surgery, the mean SE decreased slightly (myopic regression) over 10 years (Figure 3). The mean regression and regression per year are given in Table 2. In eyes that did not undergo retreatment, the rate of regression per year rate slowed down during 10 years of follow-up. Given that

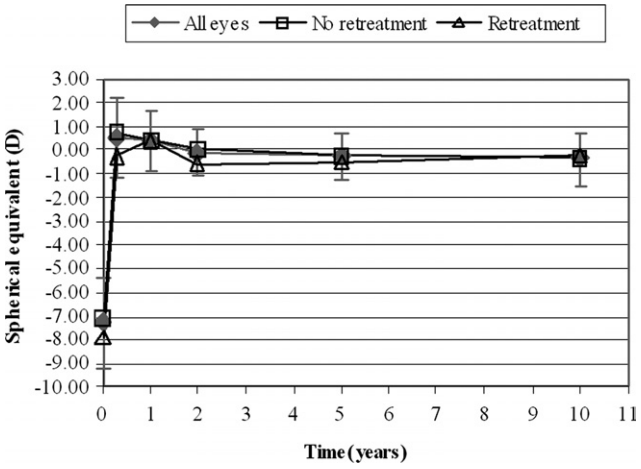

FIGURE 2. Graph showing the mean value of the spherical equivalent (SE) before surgery and three months, one year, two years, five years, and 10 years after LASIK for the 97 myopic eyes in the study. Primary procedures and retreatments are grouped together and separately. Errors bars represent the standard deviation.

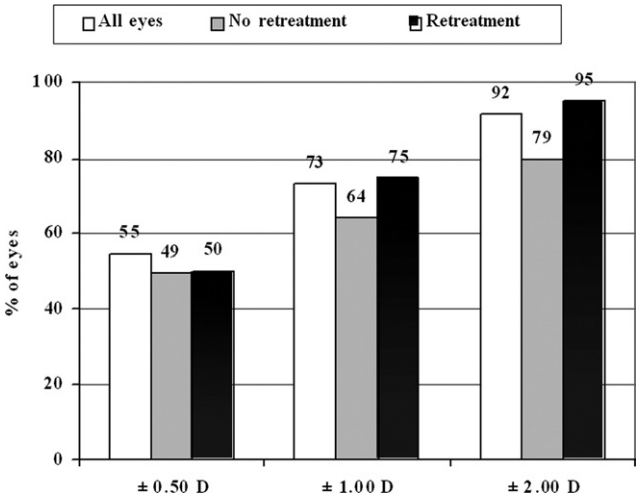

FIGURE 3. Bar graph showing the percentage of eyes within ± 0.50 D, ± 1.00 D, ± 2.00 D emmetropia (in terms of SE) at 10 years after LASIK for the 97 eyes globally and separately in eyes with and without retreatments.

most of the retreatments were performed between three months and five years of follow-up, the regression rate in eyes that undergone retreatment were influenced by retreatments in this period, and therefore, the statistical significance of difference in regression between the no retreatment and retreatment groups was not analyzed for the early follow-up periods. The correlation between regression vs age, preoperative SE, preoperative corneal power, attempted correction vs regression (for all patients, no retreatment, and retreatment groups) is demonstrated in Table 3.

• **CORNEAL STABILITY:** The mean corneal power slightly increased (0.44 D) between three months and 10 years (Figure 4, Left). Also, a slight decrease (0.15 D) in the mean topographic cylinder was observed over 10 years (Figure 4, Right).

• **VISUAL OUTCOME:** The safety index was 1.08 at 10 years. Figure 5 shows the percentage of eyes that lost or gained Snellen lines (safety) at 10 years. Fifty-one (52.6%) of 97 eyes demonstrated an increase in BSCVA and 34 eyes (35%) demonstrated no change. Only five (3.1%) of 97 eyes lost more than two lines of BSCVA: one eye lost nine lines of BSCVA because of a corneal ulcer that developed after dry eye because of radiotherapy for malignancy, but had 1.0 (20/20) vision at the five-year follow-up; one eye lost five lines of BSCVA because of macular choroidal neovascular membrane; and the other three eyes lost three lines because of myopic maculopathy. The efficacy index was 0.88 at 10 years. Figure 6 shows the preoperative BSCVA and postoperative UCVA percentage of eyes. The mean UCVA and BSCVA over time is demonstrated in Figures 7 and 8, respectively.

• **COMPLICATIONS:** The complications seen after LASIK during 10 years of follow-up are given in Table 4. Fine flap striations, observed in two eyes of two patients, did not affect visual acuity and remained unchanged during follow-up, and no surgical interventions were performed for them. Both epithelial ingrowth and flap melting were located peripherally in all eyes, were never wider than 2.0 mm, progressed very slowly, and did not affect UCVA, BCVA, or corneal astigmatism. Only one eye had punctal keratitis between three months and one year. Postoperative haze or scarring in the stromal bed was minimal. Haze was never worse than mild throughout the follow-up. No eye developed corneal ectasia in the long-term.

DISCUSSION

• **LONG-TERM REFRACTIVE PREDICTABILITY AND STABILITY:** In this study, we showed the long-term outcomes of patients with low to moderate myopia 10 years after LASIK surgery. We found that 73% (64% for the no retreatment group and 75% for the retreatment group) of eyes were within ± 1.00 D and 92% were within ± 2.00 D 10 years after LASIK. These results are similar to those of previous short-term follow-up studies of LASIK for moderate myopia: O'Doherty and associates and Pallikaris and Siganos, with a long-term follow-up of six years, found that between 33% and 66% of eyes were within ± 1.00 D after myopic LASIK[9,10]; other authors,[11,15–19] in studies of LASIK for moderate myopia with shorter than 12 months of follow-up, found that between 40% and 85% of eyes were within ± 1.00 D after surgery.

TABLE 2. Mean Values and Standard Deviations of Regression after Laser In Situ Keratomileusis for Myopia of up to −10 Diopters

	All Eyes (n = 97)	No Retreatment (n = 77)	Retreatment (n = 20)	*P* value*
Regression (D)				
Three mos to 10 yrs	−1.04 ± 1.73	−1.22 ± 1.44	−0.33 ± 2.48	.151
One to 10 yrs	−0.91 ± 1.44	−0.90 ± 1.31	−0.96 ± 1.84	.730
Two to 10 yrs	−0.39 ± 1.07	−0.46 ± 0.90	−0.12 ± 1.57	.574
Five to 10 yrs	−0.23 ± 1.07	−0.26 ± 1.05	−0.13 ± 1.18	.499
Regression per year (D/yr)				
Three mos to 10 yrs	−0.10 ± 0.18	−0.12 ± 0.15	−0.03 ± 0.25	.151
One to 10 yrs	−0.10 ± 0.16	−0.10 ± 0.15	−0.11 ± 0.20	.730
Three mos to one yr	−0.24 ± 1.73	−0.54 ± 0.99	0.63 ± 2.23	.033
One to two yrs	−0.48 ± 1.10	−0.33 ± 0.76	−1.03 ± 1.80	.045
Two to five yrs	−0.07 ± 0.37	−0.10 ± 0.35	0.04 ± 0.45	.039
Five to 10 yrs	−0.05 ± 0.21	−0.05 ± 0.21	−0.03 ± 0.24	.499

D = diopters; yrs = years; mos = months.

*Significance of difference between no retreatment and retreatment groups by Mann–Whitney *U* test.

TABLE 3. Correlation (Spearman Coefficient) between Different Ocular Variables and the Regression Value after Laser In Situ Keratomileusis for Myopia of up to −10 Diopters*

Parameter	All Eyes (n = 97)	No Retreatment (n = 77)	Retreatment (n = 20)
Time period (regression/yr)	Two to 10 yrs	Three mos to 10 yrs	Two to 10 yrs
Age	−0.11 (0.32)	−0.09 (0.42)	−0.18 (0.35)
Preoperative SE	0.12 (0.27)	0.18 (0.11)	0.17 (0.51)
Preoperative C power	0.06 (0.59)	−0.03 (0.79)	0.09 (0.73)
Attempted correction	0.12 (0.29)	0.20 (0.09)	0.12 (0.66)
Achieved correction	0.37 (0.06)	0.42 (0.03)†	0.34 (0.09)
Change in C power	0.25 (0.24)	0.17 (0.15)	0.33 (0.19)
Preoperative CT	0.24 (0.21)	0.18 (0.11)	0.22 (0.20)
Ablation depth	0.11 (0.36)	0.03 (0.85)	0.10 (0.72)
Calculated RSB thickness	0.24 (0.21)	0.21 (0.31)	0.22 (0.27)
Postoperative RSB thickness	0.18 (0.34)	−0.01 (0.95)	0.14 (0.59)
Change in CT	−0.08 (0.53)	−0.07 (0.62)	−0.12 (0.72)

C = corneal; CT = corneal thickness; mos = months; yrs = years; RSB = residual stromal bed; SE = spherical equivalent.

*All data are in the Spearman correlation coefficient (statistical significance).

†Statistically significant.

Some previous studies suggested that myopic ablations were accompanied by a hyperopic shift and that the magnitude of the hyperopic shift increased with the magnitude of attempted correction.[20,21] Similar to the long-term studies of PRK for myopia,[22–24] we could not observe a significant hyperopic shift after LASIK for moderate myopia. This could be because the follow-up examinations began at three months; therefore, if the hyperopic shift occurred within three months after LASIK, our study may have overlooked it.

Myopic regression is a universal phenomena in eyes that have undergone excimer laser correction for moderate myopia.[25] Previous studies with less than one year of follow-up, found an average regression rate of between −0.50 and −1.00 D after laser refractive correction of moderate myopia.[11,15–19] In our study, we observed an average myopic regression of −1.22 ± 1.44 D in 77 eyes that did not undergo retreatment over 10 years of follow-up, implying a regression rate of −0.12 ± 0.15 D per year. However, this rate gradually decreased from −0.54 ± 0.99 D per year between three months and one year to −0.05 ± 0.21 D per year between five and 10 years, suggesting that myopic regression stabilizes between two to five years after LASIK for moderate myopia. Many factors may lead to myopic regression, such as epithelial hyperplasia, corneal steepening because of corneal thinning, change in corneal

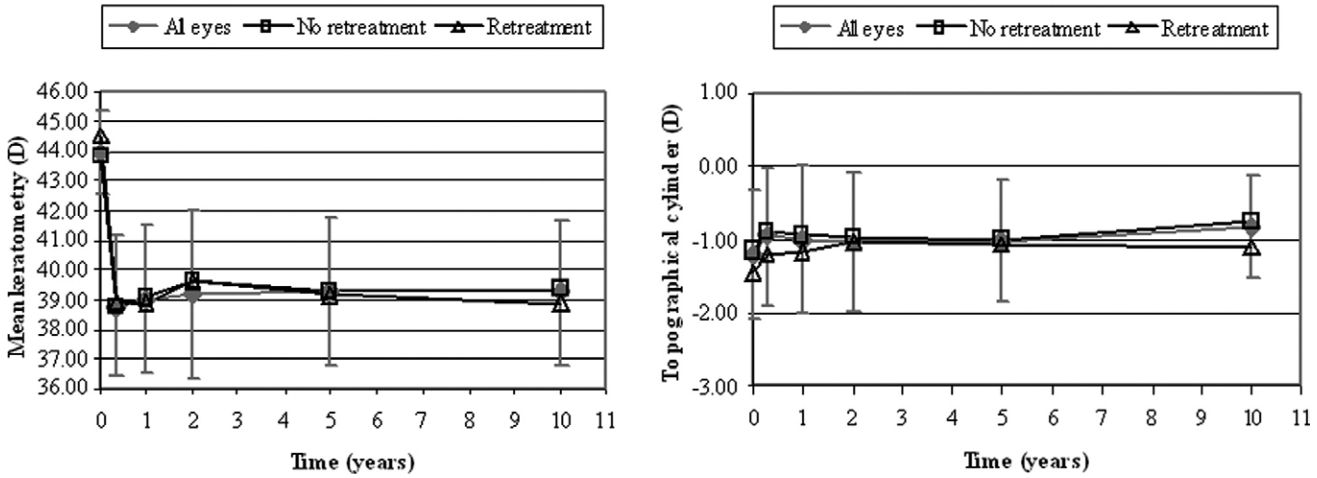

FIGURE 4. Graphs showing the (Left) corneal power and (Right) topographical cylinder before surgery and three months, one year, two years, five years, and 10 years after LASIK for high myopia. Primary procedures and retreatments are grouped together and separately. Errors bars represent the standard deviation.

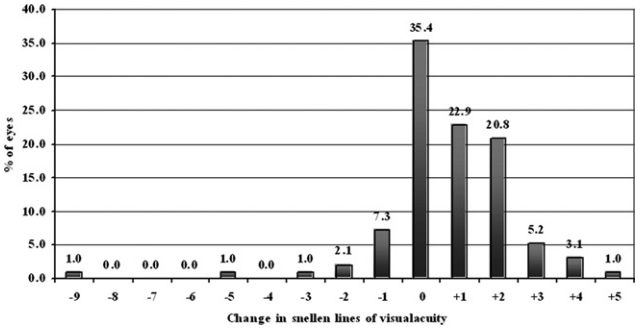

FIGURE 5. Graph showing the number of lines of best spectacle-corrected visual acuity (BSCVA) gained and lost at 10 years after LASIK for the 97 myopic eyes (safety).

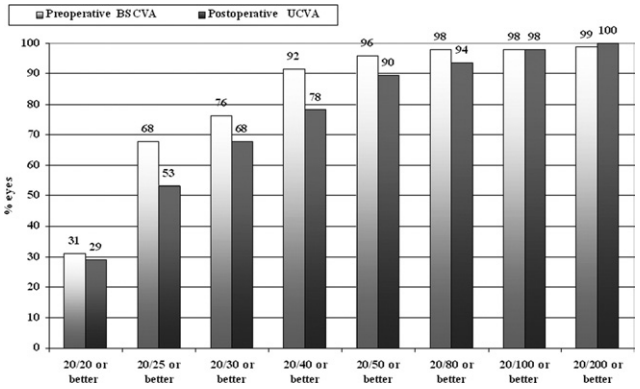

FIGURE 6. Bar graph showing the cumulative distributions of preoperative BSCVA and postoperative uncorrected visual acuity (UCVA) of the 97 eyes 10 years after LASIK for low to moderate myopia (efficacy).

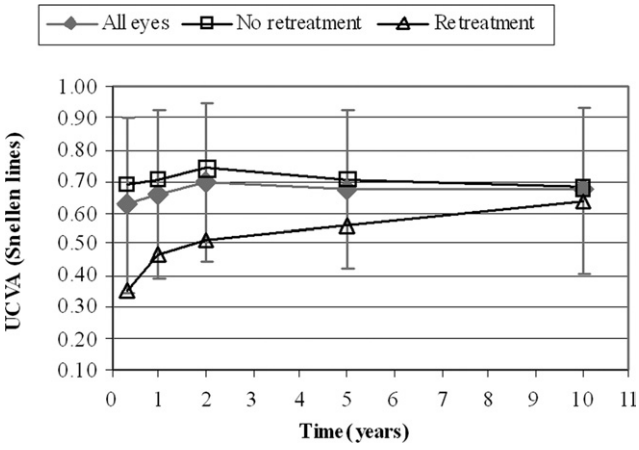

FIGURE 7. Graph showing the mean value of the UCVA before surgery and three months, one year, two years, five years, and 10 years after LASIK for the 97 myopic eyes in the study. Primary procedures and retreatments are grouped together and separately. Errors bars represent the standard deviation.

biomechanics, increase in axial length, and lenticular sclerosis.[25] In our study, we found a significant correlation between myopic regression and the achieved correction and change in corneal power, which implies that myopic regression increases with higher corrections.

• **CORNEAL STABILITY:** Progressive regression was suggested to occur because of reduced structural corneal integrity after flap creation and laser ablation, which may lead to progressive corneal ectasia in the long-term.[26] From the topographic standpoint, we observed a slight increase in the mean corneal power between three months and 10 years, and the mean corneal cylinder remained relatively stable up to 10 years. Taking into account that topography map (corneal power) underestimates achieved correction,[27,28] the increase in corneal power may explain at least in part the myopic regression observed in this study.

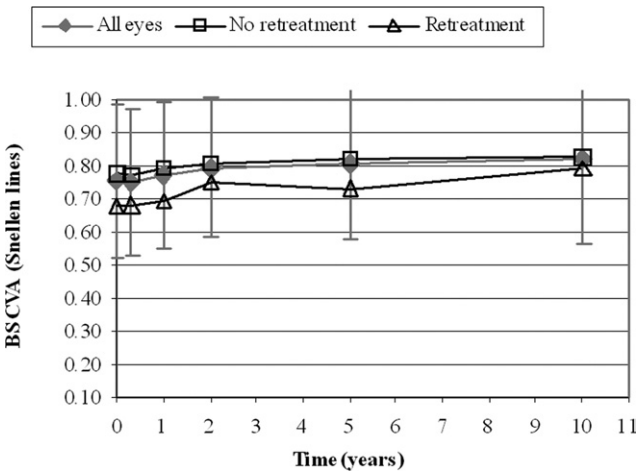

FIGURE 8. Graph showing the mean value of the BSCVA before surgery and three months, one year, two years, five years, and 10 years after LASIK for the 97 myopic eyes in the study. Primary procedures and retreatments are grouped together and separately. Errors bars represent the standard deviation.

In this study, we did not find significant correlations between regression vs ablation depth, change in corneal thickness, and RSB thickness. Moreover, corneal thickness seemed to remain stable during 10 years of follow-up. These observations may indicate that regression resulting from chronic stromal remodeling leading to corneal ectasia is a less likely event after LASIK for moderate myopia.

• **RETREATMENTS:** Our retreatment rate was 20.6%, which was similar to the previous reports of laser refractive surgery for moderate myopia,[11,15–19] which found a retreatment rate of between 20% and 30% after PRK or LASIK for moderate myopia. Similar to Peréz-Santonja and associates, retreatments in our study seemed to be safe and did not seem to increase the rate of regression compared with the eyes that had not undergone retreatment.[29] In addition, we could not find a significant difference in corneal power, topographical cylinder, corneal thickness, or RSB thickness at 10 years between eyes that underwent retreatment and eyes that did not undergo retreatment.

• **VISUAL OUTCOME:** Regarding the visual acuity, the safety score was 1.08 and the efficacy index was 0.88. The high improvement rate in BSCVA in eyes that underwent LASIK for high myopia may be explained by an increase in the size of the image on the macula.[30] Only five eyes lost more than two lines of BSCVA because of posterior segment-related complications (myopic maculopathy, three eyes; retinal detachment, one eye; neovascular membrane, one eye). At 10 years, 78% of eyes had 20/40 or better of UCVA, similar to previous studies of LASIK for moderate myopia that reported between 46% to 87% of eyes achieved UCVA of 20/40 or better after six years of follow-up.[9,10] Improvements in the nomograms to prevent undercorrection and to compensate for myopic regression have led to better efficacy after LASIK for moderate myopia.

The UCVA and BSCVA showed good stability during follow-up. We observed an increase in UCVA between three months and two years, which in part may be because of the retreatments. Retreatments also slightly increased the UCVA and BSCVA.

• **LATE COMPLICATIONS:** Previous reports identified high myopia, forme fruste keratoconus (FFKC), low RSB thickness, and multiple enhancements as risk factors for the development of ectasia after LASIK.[12] In the present study, no eyes developed corneal ectasia in 10 years, and 20 (20.6%) of 97 eyes underwent retreatments, but no eyes had preoperative FFKC on the topography. In addition, only a limited number of eyes had postoperative RSB thickness of less than 250 μm. Although ectasia were reported in eyes with more than 250 μm of RSB thickness after LASIK or even after PRK,[12,31] our results suggest that if thin RSBs are avoided, ectasia is not a very probable event after LASIK for low to moderate myopia.

Haze or scarring in the interface was minimal or absent after LASIK. Complications such as wrinkles in the flap and dot remnants in the interface were rare and should be avoided by using proper surgical technique. Although epithelial ingrowth in the interface was rare and usually did not progress, it seems to be a risk factor for flap melting. Flap melting usually developed on an epithelial ingrowth area and did not progress or progressed very slowly. None of these complications led to more than two lines of BSCVA loss.

At 10 years of follow-up, significant late-phase complications attributable to LASIK were observed only in one eye of one patient, in whom a corneal ulcer developed after developing dry eye as a result of external beam radiotherapy for malignancy. Five eyes (5.1%; three eyes of two patients developed myopic maculopathy, one eye of one patient developed peripheral retinal detachment, and one eye of one patient developed choroidal neovascular membrane) developed myopia related posterior segment complications that was not attributable to the LASIK procedure itself, but rather to the myopic nature of the patient's eye.[32] Five eyes (6.6%) of five patients developed significant nuclear sclerosis that also was not related to LASIK but rather to the high myopia.[33]

In conclusion, our findings show that LASIK for myopia of up to −10 D is a safe and effective procedure in the long-term with a high rate of BSCVA increase. Only 3.1% of eyes lost more than two lines of BSCVA and 78% of eyes avoided the use of glasses. Myopic regression positively correlates with the magnitude of attempted correction, and its rate slows down with time. Retreatments for undercorrection, regression, or both were safe and did not increase the rate of regression. There was no evidence of

TABLE 4. Incident of Complications after Laser In Situ Keratomileusis for Myopia of up to –10 Diopters for Each Follow-up Visit

Complications	No. of Eyes (%)				
	Three mos	One yr	Two yrs	Five yrs	10 yrs
Surgical complications					
Epithelial ingrowth	0 (0)	2 (2.1)	3 (3.1)	3 (3.1)	3 (3.1)
Peripheral melting	0 (0)	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.1)
Punctate keratopthy	5 (5.2)	4 (4.1)	3 (3.1)	2 (1.3)	0 (0)
Flap stria	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.6)	2 (2.1)
Corneal ulcer	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
Complications related with myopia					
Cataract	0 (0)	0 (0)	1 (1.0)	4 (4.1)	5 (5.2)
Myopic maculopathy	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	3 (3.1)
RD or RD surgery	0 (0)	0 (0)	0 (0)	1 (1.0)	1 (1.0)
CNV	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.0)

CNV = choroidal neovascularization; RD = retinal detachment; mos = months; yrs = years.

significant progressive time-dependent hyperopic shift. No eye lost more than two lines of BSCVA attributable to LASIK and no eye developed corneal ectasia in the long-term. The study group is numerically very important and it represents the range of application of LASIK technique in today. However, to the best of our knowledge, the long-term outcomes (refractive stability, efficacy, and safety) of LASIK are not known. Recent advances in corneal profiles and technologies should be taken into account when comparing these results with those of more recent procedures. Further, long-term studies using advanced excimer laser algorithms and cornea analyzing systems such as optical coherence tomography, high-frequency ultrasound, and confocal microscopy are needed to evaluate the corneal anatomy and biomechanical response to understand the long-term myopic regression after LASIK.

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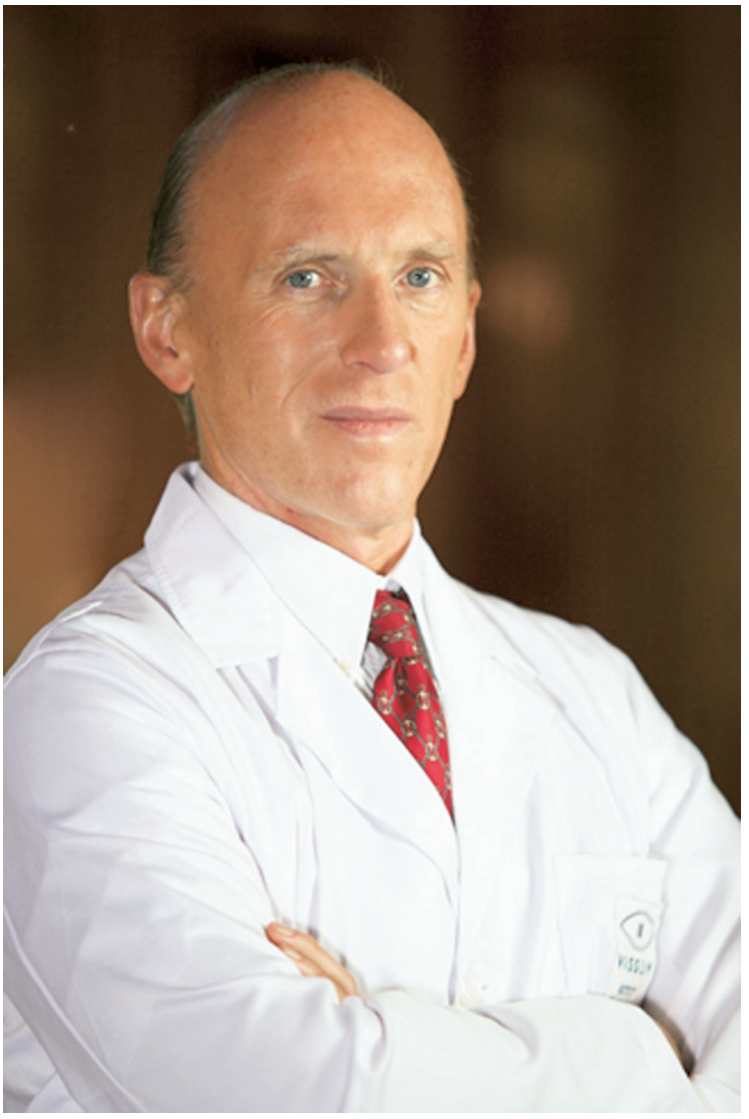

Biosketch

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